Memo of Meeting

Date: May 16, 2001
Location: 1350 Piccard Drive, Rockville, MD 20850

Representing Datasweep, Inc., 55 Almaden Blvd, San Jose, CA 95113:

Mr. Matt Holleran, vice President, Marketing & Business Development
Ms. Julie La, Market Development Manager
(By telephone link) Mr. Roger Dow, Quality Assurance Manager.

Representing the Food and Drug Administration:

Paul Motise, Consumer Safety Officer, Office of Enforcement
Tom Chin, Consumer Safety Officer, Office of Enforcement
Stewart Crumpler, Regulatory Officer, Center for Devices and Radiological Health
Mark Hackman, Consumer Safety Officer, Center for Foods and Applied Nutrition
Dennis M. Digman, Supervisory Food Technologist, Center for Foods and Applied Nutrition

The meeting was held at the request of Datasweep, to discuss the firm's software applications--a system that according to the firm's representatives provides functionality in the areas of collection and storage of lifecycle data (production to distribution) for medical devices. Data include production information, employee training, and product testing and repair information. All transactions are recorded with a secure computer generated time stamped audit trail. Web based data access allows for collaboration and work over the internet.

At the start of the meeting we explained that FDA does not formally review, approve or disapprove of products and services that enable people to meet agency regulations. We emphasized that our meeting was for the purpose of information exchange.

By way of background, the representatives explained that about 15 % of their customers are in FDA regulated industries and the number is growing.

The representatives demonstrated their software, as installed on a laptop computer. They explained how their software can interface to a firm's manufacturing and testing systems and how sequencing of key steps is ensured via software controls. End user accounts can be configured for different privileges.

We discussed how the system implements electronic signatures. E-sigs are based on identification codes in combination with passwords, although this can be supplemented with biometric technologies. Password permissible lifecycles are configurable, as is maximum password length. A dictionary look-up feature can ensure that passwords are not words found in a dictionary.

E-sig manifestations include the signer's printed name, date/time of signing and what the signature means.

Regarding electronic copies of the electronic records, the system can export to MS Excel format. Likewise, audit trails can be exported to Excel format or to an XML format.

Audit trails retain operator deletions; data are not overwritten but are retained in a transaction log.

We discussed system validation. The representatives said they were willing to have their customers or third parties audit their software development activities, and commented that they have been subject to several such audits.

The meeting lasted about two hours.

cc:
FDA Attendees
Part 11 Dockets
HFA-224

P. Motise
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